

REMARKS

Claims 1-16, 18 and 21-28 are pending in this application. By this Amendment, claims 1, 8, 16, 18 and 22 are amended, claims 19 and 20 are canceled without prejudice to or disclaimer of the subject matter recited therein, and claims 27 and 28 are added. Support for the amendments to claims 1 and 16 and new claims 27 and 28 can be found in the specification at least at page 6, line 16 - page 7, line 4, page 8, lines 8-28, page 39, lines 15-28 and page 41, line 28 - page 42, line 14; and support for the amendment to claim 8 can be found in the specification at least at page 29, line 23 - page 30, line 28 and page 43, lines 10-30. Claims 18 and 22 are respectively amended for form and dependency. No new matter has been added.

The courtesies extended to Applicants' representative by Examiner Saucier at the interview held October 2, 2009, are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below, which constitute Applicants' record of the interview.

I. Information Disclosure Statement

The Office Action does not consider references 1-3, 6, 12, 17, 18 and 22 of the PTO Form 1449 filed with the January 16, 2009 Information Disclosure Statement (IDS) because either the references allegedly do not have a statement of relevance or the citation is incomplete. Applicants respectfully traverse the Office Action's assertions for at least the reasons discussed below, and as agreed during the interview, the Examiner will consider the references in view of the discussion below.

With respect to the French references, references 1 and 2 of the January 16 Information Disclosure Statement, the Office Action asserts that these references still lack an explanation of relevance. The Office Action asserts that the search report enclosed with the January 16 IDS merely gives the citations of the foreign patents without a statement of

relevance. However, MPEP §609.04 III states that: 1) "the requirement for a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office;" and 2) "[t]his may be ... merely an 'X,' 'Y,' or 'A' indication on a search report." The Search Report enclosed with the January 16 IDS indicated that references numbers 1 and 2 are of "A" and "X" categories, respectively.

With respect to the reference 6, the Office Action asserts that the reference is illegible. However, as indicated in the January 16 IDS, Applicants submitted with the January 16 IDS a more legible copy of this reference obtained from the New York Times website. This copy is scanned with the alleged illegible copy of the reference on the U.S. Patent and Trademark Office's website.

With respect to references 3, 12, 17, 18 and 22, the Office Action asserts that the January 16 IDS provided incomplete citations. These assertions are respectfully traversed.

Applicants respectfully assert that these references as cited in the January 16 IDS satisfy the requirements of 37 C.F.R. §1.98(b), because they include author (if any), title, relevant pages of the publication, date and place of publication (which refers to the name of the journal, magazine, or other publication in which the information being submitted was published).

With respect to references 12 and 18, the Office Action asserts that the inclusive page numbers are not included. However, there are no page numbers on those publications, and thus these citations should be considered to be complete.

With respect to references 3, 12, 17 and 22, the Office Action asserts that the references lack the journal name or book name. With respect to references 3 and 12, these references are Abstracts published in trade conference publications. Thus, the place of publication, and the publication in which the information submitted was published, was

provided. Additionally, reference 3 was also published in the Scandinavian Journal of Urology and Nephrology, Supp. 54, 1980. With respect to reference 17, the publishing company was provided on the January 16 PTO Form 1449. Applicants are not aware of any book name for this reference, and thus this citation should be considered to be complete.

With respect to reference 22, the name of the book was provided on the January 16 PTO Form 1449 - "Metabolism of Xenobiotics."

Thus, the January 16 IDS complied with the IDS requirements set forth in 37 C.F.R. §1.98(b). The Examiner is requested to initial and return to the undersigned a copy of the Form PTO-1449. For the convenience of the Examiner, a new PTO Form 1449 is attached that lists references 1-3, 6, 12, 17, 18 and 22 as references 1-8, respectively.

II. Double Patenting Rejections

Claims 1-16 and 18-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-47 of copending Application No. 11/802,064, and are provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-28 of copending Application No. 11/802,059. Because the rejections are provisional and this application is the earlier filed application, Applicants will address the rejections when the claims are otherwise in condition for allowance.

III. The Claims Satisfy The Requirements of 35 U.S.C. §112, Second Paragraph

Claims 8, 13-15, 18-22, 24 and 26 are rejected under 35 U.S.C. §112, second paragraph. The rejection of canceled claims 19 and 20 is moot, and the rejection of the remaining claims is respectfully traversed.

With respect to the rejection of claims 13-15, the Office Action asserts that it cannot be determined what degree of relationship is required with respect to "the sensed characteristics relate to ..." because all characteristics of the organ may be said to be related to one another as the organ is an isolated, discrete functioning unit and is being maintained in

a metabolically active state. The Office Action further asserts that there is no nexus between the "sensed" characteristic and the relationship to the parameter of organ viability. These assertions are respectfully traversed.

For example, claims 13-15, which depend from claim 5, further recite how the sensed characteristics relate to at least one of effluent and organ. For example, claim 13 recites that the sensed characteristics relate to at least one of adsorption, distribution, metabolism and excretion. Thus, one of ordinary skill in the art would understand that the sensed characteristics of at least one of the effluent and the organ sensed by a sensor in claim 13 relate to adsorption, distribution, metabolism and/or excretion of the effluent and/or organ. Similarly, with respect to claims 14 and 15, one would understand that the sensed characteristics of at least one of the effluent and the organ relate to pharmacokinetics, pharmacodynamics and/or toxicity of the effluent and/or organ or what the substance is doing to the at least one organ and what the at least one organ is doing to the substance. Thus, as discussed during the personal interview, one of ordinary skill in the art would understand the relationship between the sensed characteristics and at least one of the effluent and organ.

With respect to the rejection of claims 8, 18, 24 and 26, the Office Action asserts that the sensing may be done by a human in a non-empirical manner. However, as discussed during the interview, claims 8 and 18 each recite that the sensing is performed by a sensor.

Claims 24 and 26 depend from claim 18.

With respect to the rejection of claims 21 and 22, the Office Action asserts that these claims ultimately depend from claim 1, but do not further limit the independent claim.

Claims 21 and 22 depend from claims 1 and 16 and each recite that the step of analyzing comprises monitoring the organ, generating the data of the organ and analyzing the data to determine whether the at least one organ is suitable to be transplanted. These features are not presently recited in claims 1 and 16. Thus, as discussed during the interview, Applicants

respectfully assert that these features recited in claims 21 and 22 further limit independent claims 1 and 16.

Thus, for at least these reasons, Applicants respectfully assert that the claims satisfy the requirements of 35 U.S.C. §112, second paragraph. Withdrawal of the rejection is thus respectfully requested.

IV. The Claims Satisfy The Requirements of 35 U.S.C. §112, First Paragraph

Claims 1-16 and 18-26 are rejected under 35 U.S.C. §112, first paragraph, for allegedly not complying with the written description and enablement requirements. The rejections of canceled claims 19 and 20 are moot, and the rejections of the remaining claims are respectfully traversed.

The Office Action asserts that the claims do not satisfy:

- 1) the written description requirement because the specification does not describe the construction of the sensors or their purchase and what constitutes suitability or non-suitability for transplantation based on the data gathered, i.e., what type of data, how is the determination as to suitability or non-suitability made, and what is indicative of organ viability; and
- 2) the enablement requirement because there is no explanation of the nexus between the analyses of a parameter and the determination of the suitability for transplantation.

These assertions are respectfully traversed.

The claims satisfy the written description and enablement requirements because: 1) one of ordinary skill in the art could make or use the invention from the disclosure coupled with the information known in the art without undue experimentation; and 2) the specification describes the claimed invention in sufficient detail that one of ordinary skill in the art can

reasonably conclude that the inventor had possession of the claimed invention. See, e.g., MPEP §§2164 and 2163, respectively.

As discussed during the personal interview, Applicants respectfully assert that the specification, for example, on page 29, line 23 -page 31, line 12, page 37, line 21 - page 38, line 20, page 39, line 10 - page 40, line 23, page 42, lines 4-25 and page 43, line 10 - page 46, line 10, and Figures 28-31, describe the sensors and how the sensed effluent characteristics can be used to determine the organ viability of an organ.

Thus, for at least these reasons, the claims satisfy the requirements of 35 U.S.C. §112, first paragraph. Withdrawal of the rejections is thus respectfully requested.

V. The Claims Define Patentable Subject Matter

Claims 1-16 and 18-26 are rejected under 35 U.S.C. §103(a) over International Patent Publication No. WO 94/06292 to Sadri in combination with International Patent Publication No. WO 98/09166, to Dietz et al. (hereinafter "Dietz"), International Patent Publication No. WO 96/29865 to Fahy et al. (hereinafter "Fahy") and Journal Publication "The In-Vitro Inhibition of Rat Alloantigen Presentation by Immunotoxins-Implications for Allografting," Clin. Exp. Immunol. (1989) 76, 132-137 by Wiley et al. (hereinafter "Wiley"), or Journal Publication "The Effectiveness of Anti-IA-Immunotoxins in the Suppression of MLR^{1,2}," Transplantation Vol. 42, No. 2 by Nakahara et al. (hereinafter "Nakahara") and "Handbook of Human Tissue Sources", Chapter 3, page 72, by Eiseman et al. (hereinafter "Eiseman") in light of the statement from "Human Tissue and Organ Resource for Research", from National Institutes of Health (hereinafter "NIH statement"). The rejection of canceled claims 19 and 20 is moot, and the rejection of the remaining claims is respectfully traversed.

As tentatively agreed during the personal interview, none of the applied references teaches or would have rendered obvious at least one of restoring and maintaining organ viability of the at least one organ; analyzing the at least one organ to determine whether the at

least one organ is suitable to be transplanted; and based on a determination that the at least one organ is not suitable to be transplanted, further comprising the steps of perfusing, contacting and gathering as recited in independent claims 1 and 16.

The Office Action acknowledges that Sadri is silent with respect to "the suitability or unsuitability for transplantation of the organ to be tested," but asserts that it can be considered to be open to the use of both these subsets of organs. The Office Action further asserts that: 1) the use of an organ which is unsuitable for transplantation in a method of research such as testing compounds in physiological or pharmaceutical research as taught by Sadri is well within the purview of one of skill in the art and it is known that banks have been made available to researchers for the express purpose of donating organs unsuitable for transplantation for use in research; and 2) one of ordinary skill in the art may use an organ, which has been determined to be unsuitable for transplantation, in the absence of evidence to the contrary especially because such banks and exchange resources have been instituted for research on such unsuitable organs. Also, one of ordinary skill in the art would have been motivated at the time of invention to make these substitutions in order to obtain the results as suggested by the references with a reasonable expectation of success. These assertions are respectfully traversed.

While Applicants disagree with the above reasoning and alleged scope of the art, in addition, Sadri fails to disclose the step of at least one maintaining and restoring the organ before analyzing to determine whether the organ is unsuitable for transplantation, as recited in independent claims 1 and 16. Sadri is silent to how the organs tested are procured. Sadri also does not teach testing an organ that had its organ viability restored.

The other applied references do not remedy the above-described deficiencies of Sadri. For example, as acknowledged by the Office Action, Eiseman states that the Human Tissues and Organs for Research (HTOR) unit focuses on retrieval and distribution of tissue and

organs. Eiseman states that the HTOR unit focuses on the retrieval and distribution of tissues and organs from autopsies and surgical procedures, and specimens obtained from eye and tissue banks. Eiseman does not disclose the reasons and method of how these organs are determined to be discarded. Also, Eiseman does not state that the HTOR unit has a protocol requiring that the organ viability of these organs be restored or maintained before, during and after procurement. Thus, Eiseman does not disclose the steps of at least one of restoring and/or monitoring, analyzing and determining, as recited in independent claims 1 and 16.

Further, even if the teachings of Eiseman were combined with Sadri, it would not result in the claimed invention. As discussed above, the HTOR unit does not have a protocol for restoring or maintaining the organ viability of the organs retrieved and the organs are typically frozen, in which case it is not possible to restore viability. Accordingly, one of ordinary skill in the art would not even attempt to restore or maintain the organ viability of an organ provided by the HTOR unit so as to determine whether it is suitable for transplantation, as recited in independent claims 1 and 16.

Thus, for at least these reasons, independent claims 1 and 16 are patentable over the applied references. Further, claims 2-15, 18 and 21-26, which respectively depend from claims 1 and 16, are also patentable over the applied references for at least the reasons discussed above, as well as for the additional features they recite. Withdrawal of the rejection is thus respectfully requested.

New claims 27 and 28, which depend from claims 1 and 16, respectively, are also patentable over the applied references for at least the reasons discussed above, as well as for the additional features they recite.

VI. Related Applications

The Office Action requests that a list of all copending applications that set forth similar subject matter to the present claims be provided. The following applications, two of

which are applied in non-statutory double patenting rejections, are related to this application:

1) U.S. Application No. 11/802,064; 2) U.S. Application No. 11/802,059; and 3) U.S. Patent Application No. 11/598,800.

VII. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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WPB:RBI/hs

Attachments:

PTO Form 1449
Petition For Extension of Time

Date: October 5, 2009

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